DESCRIPTION

SAMPLE ANALYSIS TOOL

5 Technical Field

[0001] The present invention relates to a sample analysis tool.

Background Art

[0002] In clinical tests, a sample analysis tool in which a pad(s) impregnated with a reagent(s) is provided on a plastic substrate has been used for various

10 purposes.   An example of such a sample analysis tool is shown in FIG. 3. FIG. 3A is a front view of the sample analysis tool and FIG. 3B is a perspective view of the same.   As shown in FIG. 3, in this sample analysis tool 110, eleven reagent pads 101 are arranged in series on a strip-shaped plastic substrate 103 along the longitudinal direction of the substrate 103.

15 No regent pads are provided one end portion of the substrate 103 (the end portion on the right in FIG. 3A), so that this portion serves as a holding portion to be pinched with fingers.

[0003] In such a sample analysis tool, reagents corresponding to test items are contained in the reagent pads, respectively.   For example, in the case of

20 urinalysis, the pads contain reagents for test items such as glucose (GLU), protein (PRO), bilirubin (BIL), urobilinogen (URO), pH, occult blood (BLD), ketone bodies (KET), nitrite (NIT), leukocytes (LEU), S.G. (specific gravity), and a color tone, respectively.   These items can be tested by impregnating the respective pads of this sample analysis tool with urine and then

25 measuring a change in color tone of each reagent either visually or with an optical analyzer.   When measuring the change in color tone with an optical analyzer, a predetermined tube containing a urine sample is set in the analyzer together with the sample analysis tool.   Then, an automatic feeder (see Patent Document 1, for example) automatically feeds the sample

30 analysis tool to an analysis part, where the analysis of the sample analysis

tool can be conducted automatically or semiautomatically. Note here that such a sample analysis tool also may be called a test piece or a test paper. However, in the case of a sample analysis tool for testing only two or three test items, the automatic feeding of the sample analysis tool set in the

5 analyzer to the analysis part may not be achieved successfully.

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Disclosure of Invention

Problem to be Solved by the Invention

[0004] The present invention was made in light of the foregoing problem,

10 and it is an object of the present invention to provide a sample analysis tool that can be fed to an analysis part of an analyzer automatically without causing any inconvenience when set in the analyzer, even in the case where the number of test items to be tested by the sample analysis tool is small.

Means for Solving Problem

15 [0005] In order to achieve the above object, a sample analysis tool according to the present invention is a sample analysis tool including a substrate and at least one reagent pad provided on the substrate, wherein a balance pad is provided on the substrate so as to adjust at least one of weight balance and friction balance of the sample analysis tool.

20 Effects of the Invention

[0006] The inventors of the present invention conducted studies to find the reasons why a sample analysis tool for testing a small number of test items cannot be fed to an analysis part of an analyzer successfully when it is set in the analyzer. As a result, the inventors found that the following is one cause

25 of the failure in successful feeding of the sample analysis tool. The sample analysis tool for testing a small number of test items has a small number of reagent pads, and besides, these reagent pads are arranged so as to concentrate on one end portion of the substrate. Thus, the sample analysis tool lacks in weight balance and thus cannot be treated well by an automatic

30 feeder or the like. Moreover, as a result of further studies, the inventors of

the present invention found that nonuniform friction in the sample analysis tool also is responsible to the fact that the sample analysis tool cannot be treated well by an automatic feeder or the like.   More specifically, in the sample analysis tool, the substrate and the reagent pad generally are formed

5   of different materials so that the friction coefficient of a portion where the reagent pads are present is different from that of a portion where a surface of the substrate is exposed.   In this case, no problem occurs when the reagent pads are arranged substantially uniformly over an entire reagent pad arrangement region of the substrate.   However, when the reagent pads are

10   arranged so as to concentrate on one end portion of the substrate, there arises a problem in that, for example, in the case where the automatic feeder or the like moves the sample analysis tool utilizing friction, only a portion with a higher friction coefficient (in general, the portion provided with the reagent pads) can be moved forward, whereas a portion with a lower friction

15   coefficient (in general, the portion where the substrate surface is exposed) hardly is moved forward.   This prevents smooth movement of the sample analysis tool by the automatic feeder.   Based on these findings, the inventors of the present invention discovered that, when a pad (containing no reagent) for adjusting at least one of weight balance and friction balance of the sample

20   analysis tool was provided on the substrate, the sample analysis tool could be treated well by the automatic feeder or the like so that it could be fed to the analysis part smoothly.   Thus, the inventors of the present invention arrived at the present invention.   Accordingly, the sample analysis tool of the present invention can be used in an analyzer without causing any

25   inconvenience even in the case where the number of test items to be tested by the sample analysis tool is small.   Thus, by the use of the sample analysis tools of the present invention, it becomes possible to treat a large number of samples efficiently.

Brief Description of Drawings

30   [0007] [FIG. 1] FIG. 1 shows an example of a sample analysis tool of the

present invention, wherein FIG. 1A is a front view of the sample analysis tool and FIG. 1B is a perspective view of the same.

[FIG. 2] FIG. 2 shows another example of a sample analysis tool of the present invention, wherein FIG. 2A is a front view of the sample analysis tool and FIG. 2B is a perspective view of the same.

[FIG. 3] FIG. 3 shows an example of a conventional sample analysis tool, wherein FIG. 3A is a front view of the sample analysis tool and FIG. 3B is a perspective view of the same.

[FIG. 4] FIG. 4 shows another example of a conventional sample analysis tool, wherein FIG. 4A is a front view of the sample analysis tool and FIG. 4B is a perspective view of the same.

[FIG. 5] FIG. 5 is an external perspective view showing an example of a test piece feeder.

Explanation of letters or numerals

[0008]

1	base
2	pole
3b	support member
4	rotating body
4e	groove
5	catching portion
6	test piece detection block
6e	partition plate
7	inclined cover
8	drum
9	base member
9b	arc-shaped portion
9c	discharging path
10	drive portion
10A	motor

	10B	driving force transmitting system
	11	storage portion
	100	sample analysis tool
	101	reagent pad
5	102	balance pad
	103	substrate
	104	pad arrangement region
	105	holding portion
	107	balance pad
10	110	sample analysis tool

Best Mode for Carrying Out the Invention

[0009] A sample analysis tool according to a first embodiment of the present invention is configured so that: the substrate is in a strip shape; one end portion of the substrate serves as a holding portion and a portion other than

15 the holding portion serves as a reagent pad arrangement region; the at least one reagent pad is provided on a side opposite to a holding portion side in the reagent pad arrangement region and the balance pad is provided on the holding portion side in the reagent pad arrangement region.

[0010] A sample analysis tool according to a second embodiment of the

20 present invention is configured so that: the substrate is in a strip shape; one end portion of the substrate serves as a holding portion and a portion other than the holding portion serves as a reagent pad arrangement region; the at least one reagent pad is provided on a side opposite to a holding portion side in the reagent pad arrangement region and the balance pad is provided in the

25 holding portion.

[0011] It is to be noted here that the sample analysis tool of the present invention is not limited to the above-described two embodiments.

[0012] In the first embodiment, the balance pad may be provided in the holding portion.

30 [0013] In the second embodiment, the balance pad may be provided in the

reagent pad arrangement region.

[0014] Furthermore, in the present invention, the balance pad for adjusting the weight balance may be provided on a rear surface of the substrate, taking a surface of the substrate provided with the reagent pad as a front surface.

5 [0015] In the first embodiment and the second embodiment, in the case where two or more reagent pads are provided, the reagent pads may be arranged in series along the longitudinal direction of the strip-shaped substrate.

[0016] There is no particular limitation on the use of the sample analysis

10 tool of the present invention. For example, the sample analysis tool of the present invention can be used for a general clinical test, a urinalysis, a biochemical test, a microorganism test, an immunological test, a genetic analysis, an environmental test, a test for an agricultural chemical, or an allergen test.

15 [0017] When the sample analysis tool of the present invention is used for a urinalysis, examples of a test item include glucose (GLU), protein (PRO), bilirubin (BIL), urobilinogen (URO), pH, occult blood (BLD), ketone bodies (KET), nitrite (NIT), leukocytes (LEU), S.G. (specific gravity), a color tone, ascorbic acid, a salt concentration, highly-sensitive protein, albumin,

20 creatinine, Bence-Jones protein, hormones, and physiologically active substances. In the sample analysis tool of the present invention, at least one reagent pad is provided for each test item.

[0018] The sample analysis tool of the present invention preferably is analyzed by an analyzer, but the present invention is not limited thereto.

25 For example, the sample analysis tool of the present invention may be subjected to visual observation.

[0019] FIG. 1 shows an example (the first embodiment) of a sample analysis tool of the present invention. FIG. 1A is a front view of the sample analysis tool and FIG. 1B is a perspective view of the same.

30 [0020] As shown in FIG. 1, in this sample analysis tool 100, reagent pads

101 and a balance pad 102 are provided on a strip-shaped substrate 103. One end portion of the substrate 103 (the end portion on the right in FIG. 1A) serves as a holding portion 105 to be pinched with fingers, and the region other than the holding portion 105 serves as a reagent pad arrangement

5 region 104. In this sample analysis tool 100, three reagent pads 101 are arranged in series at regular intervals along the longitudinal direction of the strip-shaped substrate 103 in an end portion of the reagent pad arrangement region 104 on a side opposite to the holding portion 105 side. Furthermore, one balance pad is provided on the holding portion 105 side in the reagent

10 pad arrangement region 104 so as to adjust at least one of weight balance and friction balance of the sample analysis tool 100 as a whole. In the sample analysis tool of the present invention, a marker for discriminating the front and rear surfaces of the substrate preferably is formed on the substrate, although such a marker is not shown in FIG. 1.

15 [0021] The material of the substrate is not particularly limited, and may be, for example, a resin, metal, glass, or the like. Also, the color of the substrate is not particularly limited, and may be white, gray, black, a chromatic color, or transparent. Furthermore, the size of the substrate is not particularly limited, and may be determined as appropriate depending on a test item, the

20 standard of an analyzer to be used, etc. For example, when the substrate is in a strip shape, the substrate may be 50 to 150 mm in length, 2 to 10 mm in width, and 0.1 to 1.0 mm in thickness.

[0022] The reagent pad and the balance pad may be formed of a filter paper, a glass fiber filter paper, a knitted fabric, a woven fabric, a nonwoven fabric, a

25 membrane filter, a porous resin sheet, a plastic film, or the like, for example. The shapes of the reagent pad and the balance pad are not particularly limited, and may be square, rectangular, circular, oval, or the like. The sizes of the reagent pad and the balance pad are not particularly limited. For example, when they are in a square shape, they may be 2 to 10 mm in

30 vertical and horizontal lengths and 0.05 to 1.0 mm in thickness. The

number of the reagent pads is not particularly limited, and may be, for example, in the range from 1 to 8. The reagent pad may be obtained by impregnating a pad material with a reagent and then forming the pad material into a predetermined shape or by forming a pad material into a

5   predetermined shape and then impregnating the pad material with a reagent. The impregnation with the reagent can be achieved by, for example, immersing the pad material in a reagent solution and then drying the pad material. Furthermore, the pad can be provided on the substrate by, for example, using an adhesive or a pressure sensitive adhesive. Examples of

10   the adhesive and the pressure sensitive adhesive include those based on polyurethane, acrylic substances, vinyl chloride, epoxy, nylon, hot melt, cyanoacrylate, rubbers, and the like.

[0023] The number of the balance pads is determined as appropriate depending on the number of the reagent pads, the positions of the reagent

15   pads, etc. For example, when the reagent pads and the balance pad are arranged in the manner as shown in FIG. 1, it is preferable that one to three balance pads are provided with respect to one to eight reagent pads.

[0024] FIG. 2 shows another example (the second embodiment) of a sample analysis tool of the present invention. FIG. 2A is a side view of the sample

20   analysis tool and FIG. 2B is a perspective view of the same. In FIG. 2, the same components as those in FIG. 1 are denoted with the same reference numerals as those therein.

[0025] As shown in FIG. 2, in the sample analysis tool according to this example, in addition to a first balance pad 102 in a reagent pad arrangement

25   region 104, a second balance pad 107 is provided in a holding portion 105. By the use of these two balance pads, at least one of the weight balance and the friction balance of the sample analysis tool can be adjusted more correctly, so that the sample analysis tool can be fed more stably in an automatic analyzer. Although FIG. 2 shows an example where the second balance pad

30   107 is larger that the first balance pad 102, the present invention is not

limited thereto. The sizes and the positions of the first and second balance pads may be determined, taking various conditions such as the size, number, and positions of the reagent pads into account. Although the two balance pads 102 and 107 were used in combination in the present example, the

5   present invention is not limited thereto and may be embodied such that a balance pad is provided only in the holding portion 105. Except for the balance pad being provided in the holding portion 105, the configuration of the sample analysis tool according to this example, i.e., the material, the size, the position, and the number of the pads, etc., is the same as that of the

10 sample analysis tool according to the above example (FIG. 1). Note here that, when the second balance pad 107 provided in the holding portion 105 is made of a material having a high friction coefficient, there is an advantageous effect that the sample analysis tool can be pinched with fingertips more easily when holding the sample analysis tool.

15 [0026] Next, an example of an automatic sample analysis tool (test piece) feeder of an analyzer to which the sample analysis tool of the present invention is applicable will be described with reference to FIG. 5.
[0027] FIG. 5 is an external perspective view showing an entire external appearance of an example of a sample analysis tool feeder to which a sample

20 analysis tool (a test piece) of the present invention is applicable. The test piece feeder shown in FIG. 5 constitutes a part of a continuous test apparatus for examining test pieces for urinalysis or the like continuously and is provided for feeding the sample analysis tools (the test pieces) to a predetermined examination portion of the continuous test apparatus one by

25 one successively.
[0028] As shown in FIG. 5, this test piece feeder is configured schematically so as to include a base 1, poles 2, support members 3b, a rotating body 4, a catching portion 5, a test piece detection block 6, an inclined cover 7, a drum 8, a base member 9, a drive portion 10, and a drum control unit. The drum

30 control unit is composed of a microcomputer and the like. Since the drum

control unit does not have a mechanical configuration and does not provide any mechanical actions, it is not shown in the drawing.

[0029] The base 1 and the poles 2 serve to lift the support members 3b above the installation surface. The support members 3b, the catching portion 5, and the test piece detection block 6 form a side wall surrounding a storage portion 11 in which a large number of test pieces are supplied and stored. The outer periphery of the rotating body 4 blocks the opening of the storage portion 11, thus serving as the bottom of the storage portion 11. The rotating body 4 serves as a test piece feeding mechanism for taking out test pieces from the storage portion 11 one by one and feeding them to the drum 8. Inside the test piece detection block 6, a photosensor that is not shown in FIG. 5 is incorporated. This sensor detects whether a single test piece fed from the rotating body 4 to the drum 8 faces up or down. Since the test piece slides down from the rotating body 4 to the drum 8, the inclined cover 7 and the base member 9 form an inclined path that is not shown in FIG. 5. In the drive portion 10, a motor 10A for impart a turning force to the rotating body 4 and the drum 8 is incorporated. The driving shaft of the motor 10A is connected to the rotation axes of the rotating body 4 and the drum 8 via a driving force transmitting system 10B including a belt and pulleys 10Ba and 10Bb. Note here that some parts of the driving force transmitting system are not shown in the drawing. This driving force transmitting system 10B, which will be described more specifically later, is divided into a driving force transmitting system for the rotating body and a driving force transmitting system for the drum. This driving force transmitting system for the drum and a drum control unit that will be described later composes a drum reversing mechanism.

[0030] Next, by taking the sample analysis tool automatic feeder shown in FIG. 5 as an example, how the inventors of the present invention arrived at the present invention will be described.

[0031] As shown in FIG. 5, as a mechanism for automatically taking out a

test piece, a groove 4e to which only a test piece(s) can be inserted is provided in the rotating body 4. Test pieces placed on the top face of the rotating body 4 are inserted into the groove 4e one by one when the rotating body 4 is rotated clockwise and counterclockwise alternately (hereinafter such a rotation is referred to as "reciprocating rotation"). Thus, the test pieces can be taken out. The test piece inserted in the groove 4e of the rotating body 4 passes through the test piece detection block 6. However, when two overlapping test pieces are in the groove 4e, a partition plate 6e provided at the entrance of the test piece detection block 6 prevents the upper test piece from entering the test piece detection block 6. After the test piece has entered the test piece detection block 6, the photosensor detects whether the test piece faces up or down. Then, the test piece is subjected to a subsequent inverting step, in which test pieces facing down are inverted so that all the test pieces face up. Thereafter, the test piece is fed to a urine dropping unit for a subsequent step, in which a predetermined amount of urine is dropped on each test piece and spectrochemical analysis is performed automatically with respect to each test piece. However, the automatic feeder using the rotating body and the drum has the following two problems.

[0032] One problem is as follows. In a sample analysis tool (a test piece) as shown in FIG. 3, when nine to eleven reagent pads are attached to the substrate 103, it is possible to take out the test piece efficiently by reciprocatingly rotating the rotating body 4 a few times. However, when the number of the reagent pads is 8 or less, the test piece cannot be taken out even if the rotating body 4 is rotated reciprocatingly ten-odd times.

[0033] The other problem is as follows. In the case where a sample analysis tool (a test piece) as shown in FIG. 3 includes eight or less reagent pads, when the test piece is inserted in the groove 4e with the test piece facing up (i.e., with the surface provided with the reagent pads facing up), a large space is provided between the partition plate 6e and the test piece. Thus, the holding portion 105 of another test piece may be lodged in this space.

[0034] Accordingly, the inventors of the present invention investigated the cause that hinders the smooth insertion of a test piece in the groove 4e. As a result, the inventors found that at least one of the weight and the friction of the test piece (see FIG. 3) was lacking in balance and concentrated on the side opposite to the holding portion 105 side (i.e., the reagent pad side) so that, during the reciprocating rotation of the rotating body 4, only the side of the test piece with a heavier weight (the reagent pad side) or a greater friction coefficient (the reagent pad side) could move on the surface of the rotating body 4 whereas the holding portion 105 side slid over the surface of the rotating body. In particular, when the test piece faced down (i.e., when the surface provided with the reagent pads faced the rotating body), only the reagent pads of the test piece were in contact with the rotating body 4, so that the resistance between the holding portion 105 and the surface of the rotating body 4 became small. This prevented the test piece from being in parallel with the groove 4e, thereby hindering the smooth insertion of the test piece into the groove 4e.

[0035] In view of the above, it was found that tasks to be addressed were preventing the test piece from being tilted with respect to the groove 4e during the reciprocating rotation of the rotating body 4 and eliminating the space between the partition plate 6e and the groove 4e. Thus, according to the present invention, a balance pad is used (e.g., attached on the holding portion 105 side) in a test piece for testing a small number of test items of, for example, eight or less. This allows the test piece to be taken out stably and efficiently, thus solving the above-described two problems.

[0036] In general, both the front and rear surfaces of the main body (substrate) of the test piece assume white as a base color. However, in order to allow the photosensor to detect whether the test piece faces up or down accurately as described above, it is preferable that a marker is formed in a portion other than the portions to which the reagent pads are attached on the surfaces of the main body. Examples of the marker include a black marker.

[0037] Hereinafter, examples of the present invention will be described along with comparative examples

Example 1

[0038] Sample analysis tools (test pieces) provided with three reagent pads and one balance pad as shown in FIG. 1 and sample analysis tools (test pieces) provided with three reagent pads and two balance pads as shown in FIG. 2 were produced. Then, ten test pieces per each type were placed on the rotating body of the test piece feeder shown in FIG. 5, and the rotating body was rotated reciprocatingly until all the test piece were taken out. The number of rotations of the rotating body was measured. The results are shown in Table 1 below.

[0039] [Table 1]

Test piece No.	three reagent pads + one balance pad	three reagent pads + two balance pads
	number of reciprocating rotations	number of reciprocating rotations
1	4	2
2	3	1
3	2	1
4	2	2
5	3	2
6	1	3
7	2	1
8	2	2
9	3	2
10	3	3

[0040] (Comparative Example 1)

Test pieces provided with eleven reagent pads as shown in FIG. 3 and test pieces provided with only three reagent pads as shown in FIG. 4 were

produced, and measurement using these test pieces was carried out in the same manner as in Example 1.   The results are shown in Table 2 below.
[0041] [Table 2]

Test piece No.	eleven reagent pads	three reagent pads
	number of reciprocating rotations	number of reciprocating rotations
1	2	11
2	3	8
3	3	9
4	1	clogged
5	2	10
6	3	9
7	2	7
8	1	16
9	2	11
10	2	7

5   [0042] As shown in Table 1 and Table 2, in the case where many reagent pads were provided, no significant differences were observed between the example and the comparative example.   However, in the case where a small number of reagent pads were provided, the number of reciprocating rotations required for taking out all the sample analysis tools (the test pieces) of the

10   examples was only 1 to 3, which was much smaller than that required for taking out all the sample analysis tools (the test pieces) of the comparative example.   The number of reciprocating rotations required for taking out all the test pieces of the comparative example was as great as 7 to 11 and besides, the occurrence of clogging was observed.   From these results, it can be said

15   that, by providing a balance pad, even a test piece for testing a small number of test items can be taken out with a significantly improved probability and

besides, the clogging can be prevented from occurring so that the test piece can be taken out stably.

Industrial Applicability

[0043]   There is no particular limitation on the use of a sample analysis tool of the present invention.   The sample analysis tool of the present invention can be used, for example, in clinical tests, biochemical tests, etc., but is particularly suitable for clinical tests that require a large number of samples to be processed with an analyzer.